DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E-0314]

Determination of Regulatory Review Period for Purposes of Patent Extension; SPIRIVA HANDIHALER

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SPIRIVA HANDIHALER and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

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Office of Regulatory Policy (HFD-013),
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SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product SPIRIVA HANDIHALER (tiotropium bromide monohydrate). SPIRIVA HANDIHALER is indicated for the long-term, once daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SPIRIVA HANDIHALER (U.S. Patent No. 5,610,163) from Boehringer Ingelheim Corporation, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 31, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SPIRIVA HANDIHALER represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SPIRIVA HANDIHALER is 3,318 days. Of this time, 2,557 days occurred during the testing phase of the regulatory review period, while 761 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became

effective: January 1, 1995. The applicant claims February 2, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 1, 1995, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the act: December 31, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for Spiriva HandiHaler (NDA 21-395) was initially submitted on December 31, 2001.

3. The date the application was approved: January 30, 2004. FDA has verified the applicant's claim that NDA 21-395 was approved on January 30, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,421 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before [insert date 60 days after date of publication in the FEDERAL REGISTER], submit to the Division of Dockets Management (see ADDRESSES) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before [insert date 180 days after date of publication

in the FEDERAL REGISTER], for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this

document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 5, 2006.

January 5, 2006.

Jane A. Axelrad

Jane A. Axelrad,
Associate Director for Policy,
Center for Drug Evaluation and Research.